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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/602,930   | 06/24/2003  | David Ernest Hartley | PA-5332-RFB         | 1860             |
| 9896   | 7590        | 09/19/2005           | EXAMINER            |                  |
| COOK GROUP PATENT OFFICE<br>P.O. BOX 2269<br>BLOOMINGTON, IN 47402 |             |                      | ISABELLA, DAVID J   |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3738                |                  |

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/602,930

Applicant(s)

HARTLEY ET AL.

Examiner

DAVID J. ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-9,12,13,22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,12,13,22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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***Status of the Claims***

Claims 1,3-9,12,13,22 are currently pending. Claim 1 has been amended.

Claims 2,10,11,14-21 have been cancelled.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3,5-9,22 and 23 are under 35 U.S.C. 103(a) as being unpatentable over Baker et al (6814748).

Baker et al discloses a 1 medical device comprising: a graft material, stent affixed to and extending from the graft material, the stent comprising plurality of struts and bends between them, the bends defining apices, and at least two spaced apart fastenings affixing the stent to the graft material, each fastening including at least one turn of an elongate flexible fiber through the graft material and around a portion of the stent wherein a first of the at least two spaced apart fastenings is laced at the apex and a second of the at least two spaced apart fastenings is laced adjacent the transition from the bend to the strut. See figure 19.

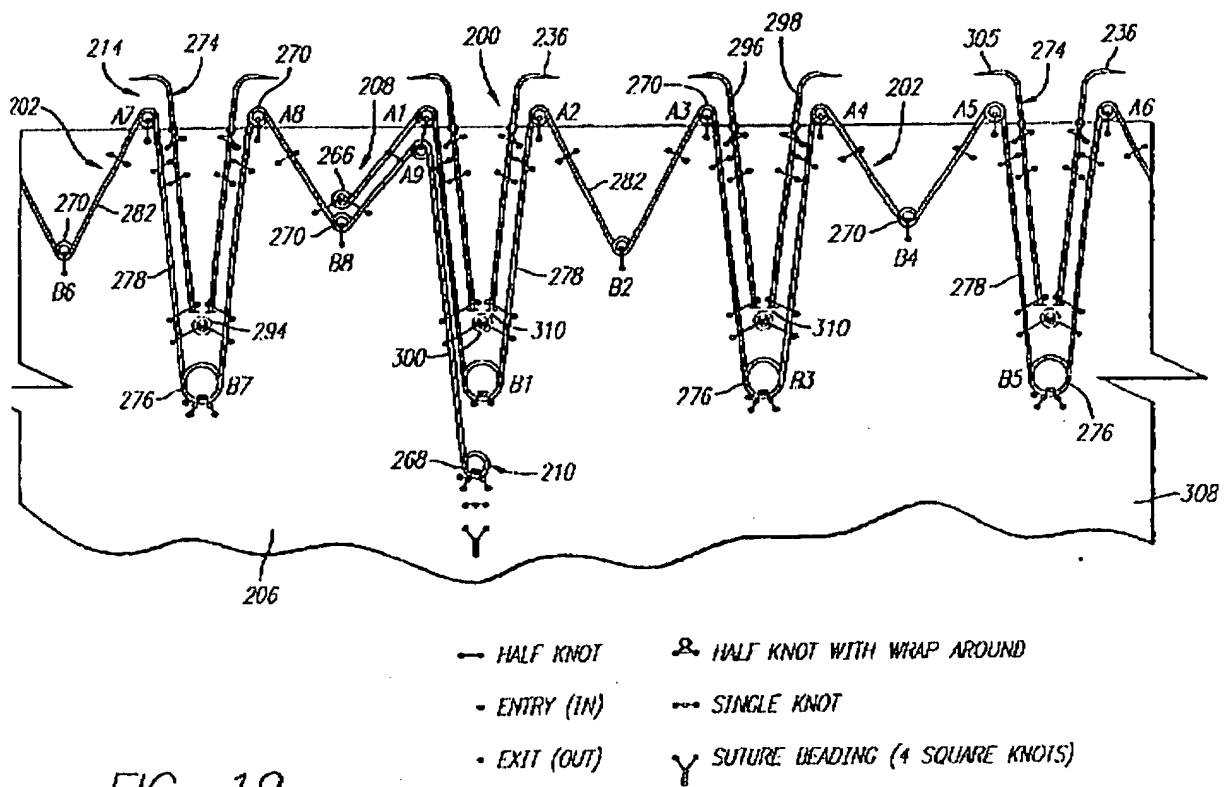


FIG. 19

Applicant argues that Baker, et al fails to illustrate a stent which is "affixed to and extending from the graft material". Examiner disagrees with applicant's arguments, the scope of the arguments does not preclude a portion of the stent extending from the material. Moreover, the claim fails to positively define the stent as extending beyond the edge of the graft and, in fact, the stent of Baker may be interpreted as extending from the graft even though being covered by the same. Accordingly, the claim as broadly worded is fully anticipated by the graft/stent combination of Baker, et al.

Applicant's amended the claim to include at least two turns of a fibre and as argued by applicant, Baker appears to use two single knots to fasten the stent to the

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graft. Examiner does not agree with applicant's interpretation of Baker. Column 10 of Baker, Baker describes that the suture material extends in and out of the wall in which knots are formed on each of the legs or struts. While Baker does not specifically describe a single suture with two turns, if not inherent, the use of two single strands knotted off about each legs or struts would essentially be functional equivalent to the single strand and two turns as claimed by applicant.

The spring means 131 is secured to the first and second ends 123 and 124 of the tubular member by suitable means such as Dacron polyester suture material 146 which is utilized for sewing the spring means onto the tubular member. This can be accomplished by a sewing operation with the suture material 146 extending into and out of the wall 126 of the tubular member and in which knots 147 are formed on each of the legs or struts 137 and 138 in such a manner so that the apices lying in the plane 141 extend outwardly and are spaced from the end on which they are mounted and in which the apices lying in the plane 142 extend just beyond the outer edge of the tubular member and in which the apices in the third plane are positioned inwardly from the outer edge.

Although two single knots is different from a single tow with two turns to fasten the stent to the graft, the use of the double strands offer essentially the same benefits to the attachment site, that of withstanding higher loads at the site. Examiner contends that, if not inherent, the manner by which the stent is attached to the graft are essentially equivalent and to use either one strand with two tows or two single strands to make the attachment of the stent more secure would have been obvious to one with ordinary skill in any art.

Claims 3,5,6,7,8,9,22 and 23 do not distinguish over the same as disclosed by Baker, et al. Claim 3, see various knots arrangements, including single, square and half knots. Claim 5, see column 19, lines 14+. Claim 6, see column 23, lines 4+. Claim 7, see column 10, lines 5+. Claim 8, see column 7, lines 1+. Claim 9, see columns 10 and 11. Claims 22, the manner by which the stitches are placed on the graft does not impart further structural distinction over the same as disclosed by Baker, et al. Claim 23, see figure 19 supra.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al (6814748) as applied to claim 1 above, and further in view of Robinson et al (5733325).

While Baker et al is silent as to the spacing of the sutures, Robinson teaches spacing the loops so as reduce stress concentration on the meshed device. To space the loops of Baker et al such that the turn of the fiber does not pass through the same portion of the meshed device would have been obvious to one with ordinary skill in the art from the teachings of Robinson.

### ***Response to Arguments***

Applicant's arguments filed 7/11/2005 have been fully considered but they are not persuasive. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "essentially entirely on the graft material with only a part of one of its bends on the edge"; stent may be subject to a large loading;) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

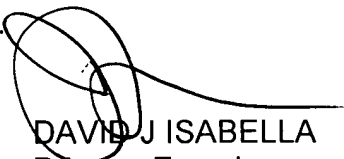
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-THURSDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
9/9/2005